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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/663,258

09/16/2003

Jose Engelmayer

H0-P02652US1

2875

26271

7590

06/29/2006

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EXAMINER

KAM, CHIH MIN

ART UNIT

PAPER NUMBER

1656

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/663,258	Applicant(s) ENGELMAYER ET AL	
	Examiner Chih-Min Kam	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 1-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/16/03; 2/23/04; 6/15/05</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group II, claims 15-51, and sub-genus of skin wounds and species of diabetic ulcer in the response filed May 30, 2006 is acknowledged. Upon reconsideration, the requirement of species election is withdrawn, and all the sub-genera and all the species in claims 26 and 29 will be considered. Therefore, claims 15-51 are examined.

### ***Claim Objections***

2. Claims 36-38 are objected because of the recitation of the term “IFN-γ”, “MIP- 1γ”, “MIP- 3γ” or “TNF-γ”. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 15-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 15-51 are indefinite because the claims lack an essential step in the method of treating a wound, or enhancing the local or systemic immune system in a subject suffering from a wound. The omitted step is the outcome of the treatment and/or effective amount of a lactoferrin composition used in the treatment. Claims 15, 17-30, 32 and 34-47 are included in

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this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

5. Claim 15 is indefinite because the claim is dependent from a non-elected claim, claim 5.

6. Claims 34 and 35 are indefinite because the claim recites the lactoferrin composition stimulates the production of a cytokine or a chemokine, or results in inhibition of a cytokine or a chemokine, it is not clear which cytokine or chemokine is stimulated, or which cytokine or chemokine is inhibited.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 16-18, 21-23 and 26-51 are rejected under 35 U.S.C. 102(b) as anticipated by Mita *et al.* (U. S. Patent 5,561,109, published October 1, 1996).

Mita *et al.* disclose a method of treating wounds caused by corneal injury by administering to a mammal patient an effective amount of lactoferrin, lactoperoxidase or a combination of lactoferrin and lactoperoxidase as active ingredient, either alone or with a excipient, where the lactoferrin and/or lactoperoxidase can be administered orally or parenterally, or as an eye drop, and the dosage is 0.01-3.0% as an eye drop (column 1, line 35-column 2, line 38; claims 16-18, 22-23 and 26-30). For example, rabbits with corneal alkali burn injury are used as an animal model for in vivo study, where 0.5% (by wt) eye drops of lactoferrin

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or lactoperoxidase dissolved in physiological saline was instilled 10 times per day at one intervals and the treatment was continued for 13 days (column 3, lines 24-column 4, line 3; claim 21). Although Mita *et al.* do not indicate administration of lactoferrin to the patient would supplement the local or systemic immune system, stimulate the production or inhibit of certain cytokines or chemokines, or inhibit the production of matrix metalloproteinases, the reference teaches the same method steps (i.e., administration of lactoferrin) as the claimed method, where the lactoferrin is expected to produce these effects (claims 31-51).

8. Claims 16-18, 21-23 and 26-51 are rejected under 35 U.S.C. 102(a) as anticipated by Boyko *et al.* (WO 02/03910, published January 17, 2000) based on the English translation provided by applicant.

Boyko *et al.* disclose a preparation of lactoferrin having antibacterial, antioxidant, detoxicating, anti-inflammatory, immunomodulating and anticarcinogenic effect is used for treating wound surface, where the preparation can be administered orally, intravenously, intracavitarily or intravesically, in the form of eye drops, inhalations or ointments, and the concentration of the active ingredient is 0.1-0.3% in a solution, the solution can be applied 2-3 times a day during a period of 3-15 days (pages 2-4; claims 16-18, 21-23 and 26-30). For example, a patient diagnosed with second stage lymphosarcoma of peripheral lymph nodes was treated with gelatin boluses containing the lactoferrin preparation, the decrease of the ulcerated area was observed on the second day after the treatment (page 8, first paragraph). Although Boyko *et al.* do not indicate administration of lactoferrin to the patient would supplement the local or systemic immune system, stimulate the production or inhibit of certain cytokines or chemokines, or inhibit the production of matrix metalloproteinases, the reference teaches the

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same method steps (i.e., administration of lactoferrin) as the claimed method, where the lactoferrin is expected to produce these effects (claims 31-51).

***Claim Rejections-Obviousness Type Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 16-51 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-14, 16, 18-22 and 35-38 of copending Application No. 10/733,621 (based on the amended claims filed March 16, 2006). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 16-51 in the instant application disclose a method of treating a wound, or enhancing the local or systemic immune system in a subject suffering from a wound by administering to the subject an effective amount of a lactoferrin composition. This is an obvious variation in view of claims 1, 3-14, 16, 18-22 and 35-38 in the copending application which disclose a method of treating a subject suffering from pain comprising the step of administering to the subject an effective amount of a lactoferrin composition, wherein the pain is associated with cancer or surgery. Both the claims of instant application and the claims of the copending application are directed to a method of treating wound or a patient having a pain from surgery by

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administering a lactoferrin composition, where a patient having a pain from surgery would be expected to have a wound. Thus, claims 16-51 in present application and claims 1, 3-14, 16, 18-22 and 35-38 in the copending application are obvious variations of a method of treating wound by administering a lactoferrin composition.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

10. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

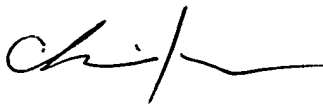
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Chih-Min Kam, Ph. D.  
Primary Patent Examiner



primary

**CHIH-MIN KAM**  
**PRIMARY PATENT EXAMINER**

CMK  
June 24, 2006